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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,286	02/16/2001	Michael B. Goshe	23-56765	5274

7590

08/15/2002

KLARQUIST SPARKMAN CAMPBELL
LEIGH & WHINSTON, LLP
One World Trade Center, Suite 1600
121 SW Salmon Street
Portland, OR 97204-2988

EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/15/2002.

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/788,286

Applicant(s)

GOSHE ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1) Applicants are advised that the term "affinity label" of claim 22 finds no antecedent basis in claim 15.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 15-19, 21 and 23 (at least part of each), drawn to an MS analysis reagent wherein the binding agent is a 1,2-diol, classified in class 568.
- II. Claims 15-19, 21 and 23, at least part of each, drawn to an MS analysis reagent wherein the binding agent is glutathione, classified in class 530, subclass 300.
- III. Claims 15-19, 21 and 23 (at least part of each), drawn to an MS analysis reagent wherein the binding agent is maltose, classified in class 536.
- IV. Claims 15-20 and 23 (at least part of each), drawn to an MS analysis reagent wherein the binding agent is biotin, classified in class 549.
- V. Claims 15-19, 21 and 23 (at least part of each), drawn to an MS analysis reagent wherein the binding agent is a nitrilotriacetic acid, classified in class 562.
- VI. Claims 15-19, 21 and 23 (at least part of each), drawn to an MS analysis reagent wherein the binding agent is an oligohistidine, classified in class 530, subclass 350.
- VII. Claims 15-19, 22 and 23 (at least part of each), drawn to an MS analysis reagent wherein the binding agent is a hapten, class 435.
- VIII. Claims 1-14 and 24-27, drawn to methods of detecting phosphorylation states, classified in class 436, subclass 545.

2) The inventions are distinct for the following reasons.

(a) Each of Inventions I-VII is unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have diverse chemical structures and functional groups as evidenced by their divergent

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classification. A reference which would anticipate or render obvious the conjugate of Invention IV defined as biotin-(CH₂)₆-NH₂ would not necessarily anticipate or render obvious the conjugate defined as OH-CH₂-CH(OH)-CH₂-COO-CH₂-SO₂NH₂ of Invention I.

(b) Inventions **a)** I-VII and **b)** VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). As an example of a materially different process of using a product, in the instant case, the product of Invention IV defined as biotin-(CH₂)₆-NH₂ could be reacted with a solid support and used to capture an avidin labeled component in a sample for analysis.

3) Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter requiring divergent fields of search, restriction for examination purposes as indicated is proper. Additionally, different patentability considerations are required for each of the inventions. A patentability determination for each of Inventions I-VII would involve a determination of the patentability of each of the compounds *per se independent of any method of use*.

4) In response to this restriction requirement applicants must elect one invention even though the requirement be traversed.

5) Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

August 14, 2002


Mary E. (Molly) Ceperley
Primary Examiner
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